DePuy Synthes
COMPANIES OF Johnson&Johnson

REUSABLE STERILIZATION CONTAINER SYSTEM.

Validated container system for the *DePuy Synthes Companies (Trauma & CMF)* instrument and implant sets.

USER'S MANUAL

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TABLE OF CONTENTS

INTRODUCTION	Product Overview	2
INSTRUCTIONS	Container Disassembly	3
	Container Filter Components and Assembly	5
	Container and Tray Assembly	9
	Container Cleaning	12
	Container Sterilization	15
	Container Aseptic Presentation	18
ADDITIONAL INFORMATION	General Precautions	22
	Preventative Maintenance Checklist	24
	Warranty	24
	Return / Repair Policy	25
	Indications	26
	Product Part Numbers	29

PRODUCT OVERVIEW

The DePuy Synthes Reusable Sterilization Container System is an assortment of rigid, reusable containers that are used to sterilize other medical devices and maintain the sterility of these devices for up to 180 days. It is the only container system that has been validated for the *DePuy Synthes Companies (Trauma & CMF)* instrument and implant sets. The container system is comprised of an anodized aluminum rivet-less case assembly (perforated lid with either perforated or solid bottom) with silicone gasket assembled together using a stainless steel dual action latching mechanism. The perforated lids and bases have perforated retention plates that are intended to secure SMS Polypropylene filters in place over the sterilant access holes to allow air evacuation and steam sterilant penetration during the sterilization cycle and to act as a barrier to microorganisms during storage, handling and transport.

The DePuy Synthes Reusable Sterilization Container System also includes single use filters and tamper-evident arrows with process indicators and data cards. The system makes use of a stainless steel lifting platform to hold graphic cases containing orthopaedic instruments and implants within the container for sterile processing.

Testing of assembled, loaded containers up to a weight of 25 lb. (11.3 kg) has demonstrated that the contents can be effectively sterilized when the validated sterilization parameters are followed*.

*Hospitals should refer to AAMI/AORN guidelines on weights and weight limit. Please refer to the Indications section for specific information regarding the types of devices and materials that are compatible with the sterilization container system.

CONTAINER DISASSEMBLY

All container components should undergo a complete decontamination process after each use. In preparation for thorough cleaning, the container should be fully disassembled and decontaminated either mechanically or manually. See Container Cleaning for complete cleaning recommendations.

1. Open the lid

Supporting the upper latch with thumb, place fingers under bottom latch plates on both ends of the container.

Gently pull upward and outward on bottom latch plates. Simultaneously open both latches. This disengages the lid from the bottom.

With the latch in the upright position, lift lid from the bottom.

2. Remove lifting platform from the container (if applicable)

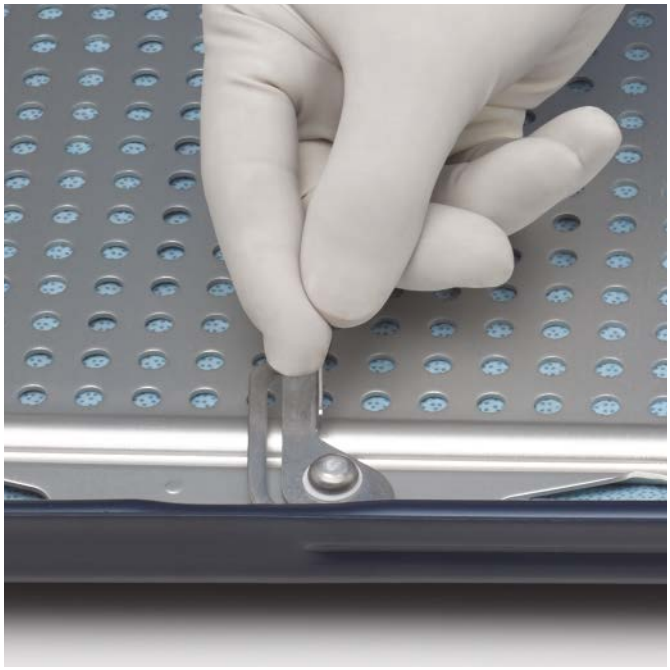
Ensure lifting platform handles are angled toward the center during removal to prevent binding of lifting platform handle with container.

3. Remove Retention Plates from container lid and bottom (if applicable)

Apply downward pressure on the retention plate near the lever and simultaneously rotate the cam lever away from the indentation protruding from the side of the lid.

Discard the used filter - do not reuse.

Remove the optional protective plate from the lid, if applicable.



4. Remove remaining single use accessories

Inspect for tamper-evident arrow fragments that might be remaining under the handles in the arrow space on both sides of the container bottom. Discard fragments.

Remove data card from container.

Note: The data card may be retained as a record.

CONTAINER FILTER COMPONENTS AND ASSEMBLY

All DePuy Synthes Sterilization Containers use the same filter (62.010.002) and are validated for pre-vacuum steam sterilization only.

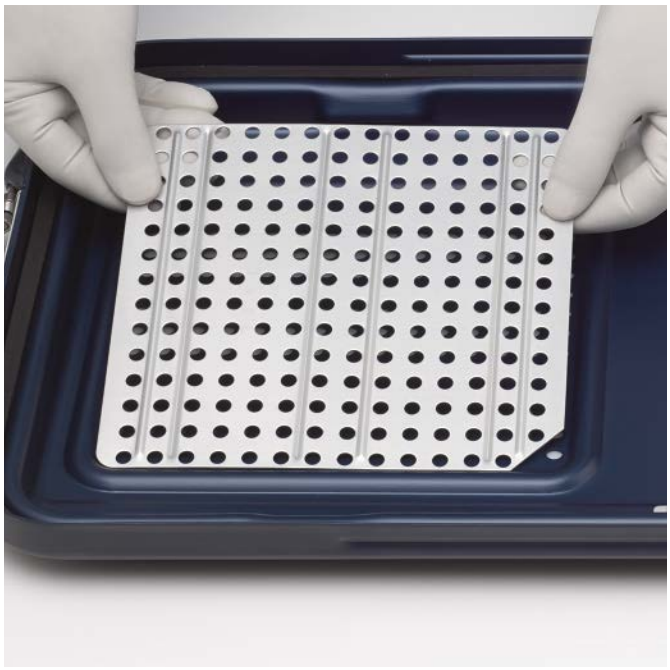
The optional protective plate is shipped with the lid of every new container. The protective plate is for use with the pre-vacuum steam sterilization modality. Validated lethality and shelf life are achieved independent of optional protective plate use (i.e., use of this plate does not have an impact on shelf life). While the offset perforations of the lid and retention plate provide additional protection to the filter material, the use of the optional protective plate helps prevent puncture of the filter material from external objects.

1.

If the optional protective plate is used in the lid, place the optional protective plate directly over the perforations (sterilant access holes).

Note: **The optional protective plates should be properly aligned with the rectangular shaped sterilant areas of the lid.**

Caution: **The optional protective plate has not been validated for use in the container bottom.**



2.

Place a new filter on top of the optional protective plate and over the entire filter ridge surrounding each sterilant access hole area in the container lid or bottom.

Alternative step if optional protective plate is not used: Place a new filter directly over the perforations (sterilant access holes) and over the entire filter ridge surrounding each sterilant access hole area in the container lid or bottom.

Note: **The filter should overlap the filter ridge on all four sides and will be secured between the filter retention plate and the lid or bottom when assembled.**

Cautions:

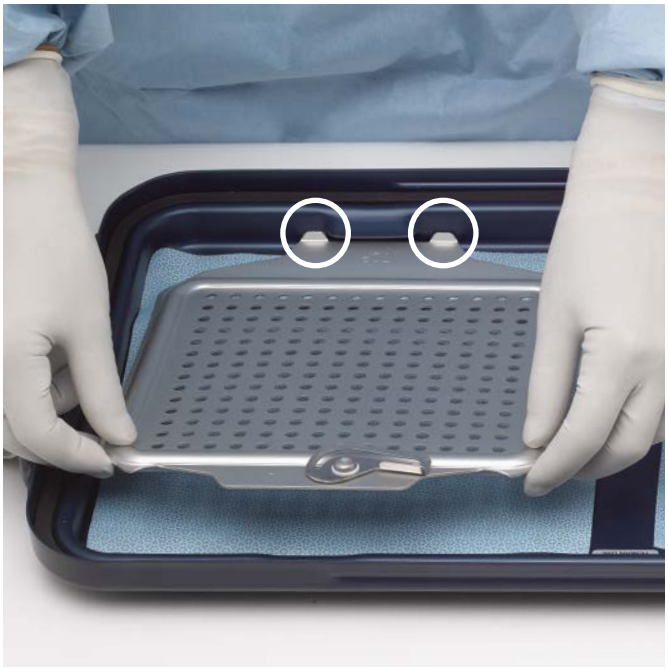
- Make sure filter does not overlap itself or become wrinkled or creased.
- Filters are for single use only and must be discarded after each process.
- Do not use more than one filter per sterilant access hole area.
- Each sterilant access (set of perforated holes) area requires one filter.
- The filter must completely cover each plate area.
- Filters other than part number 62.010.002 have not been validated for use with the DePuy Synthes Sterilization Container System.

3.

Place the retention plate on top of the filter.

Use the two alignment tabs on the filter retention plate to properly position it under the indentations.

Make sure the retention plate is firmly seated under the indentation in the container lid or base.



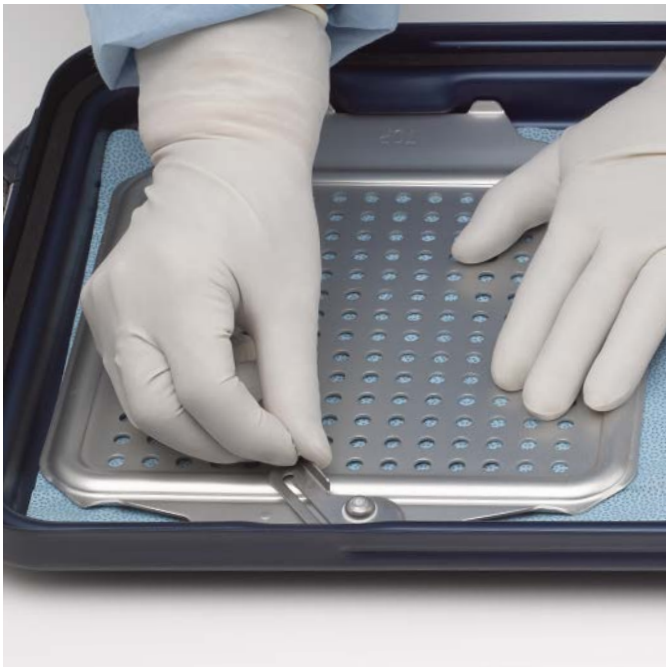
Note: **The filter retention plates are stamped "BOTTOM" or "TOP" as a guide for appropriate placement.**

4.

Apply downward pressure to the plate near the lever and rotate the retention plate lever toward the indentation protruding from the side of the container.

Note: **Make sure the lever is rotated completely to the side of the container and the retention plate is locked firmly in place.**

Caution: **The filter must be placed between the optional protective plate (if used) and the retention plate.**



Lid with assembled filter components.

CONTAINER AND TRAY ASSEMBLY

1.

Confirm that the lid (and bottom, if perforated) has the appropriate filters and retention plates in place.

2.

If needed, select the appropriately sized lifting platform and place instruments/implants set onto the lifting platform.

Note: **The use of lifting platform is required when using a perforated bottom container to hold the contents and avoid damaging the filter areas. It is not required for solid bottom containers.**

3.

Place instrument and/or implant set into the container.

Notes:

- Instrument trays from no more than one (1) loaded graphic case can be placed in the container.
- The container should never be overloaded with medical devices. Ensure devices are properly placed inside the container so nothing is protruding over the top that could interfere with closure of the lid.
- If the lifting platform is used, ensure the lifting platform handles are angled toward the center during placement of set into the container.

4.

Place an internal processing indicator, or integrator, in the set according to hospital protocols and policies. If the data card is to be used, place it in the data card block prior to putting the lid on the container.

5.

Properly seat the lid on container bottom.

LOCK THE CONTAINER

1.

Interlock lid-latch component with base latch component on both sides.

2.

Press down with smooth continuous pressure until an audible snap is heard, confirming the latch is secured.

INSERT THE TAMPER-EVIDENT ARROWS

1.

Move the carrying handle to an upright position.

2.

Orient the arrow so that the chemical indicator dot is facing outward.

3.

Insert one arrow (62.010.004) into the open channel found under the right data block that holds the data card.

4.

Advance the arrow until both sets of tabs have completely passed through the channel and are visible. When fully inserted, the tail portion of the arrow should be flush with the channel.

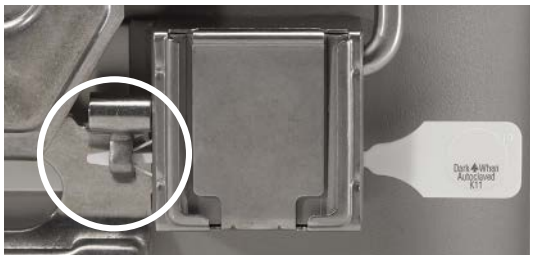
5.

Grasp the arrow end with the indicator dot and gently pull back on the arrow to ensure that it is correctly placed and secure.

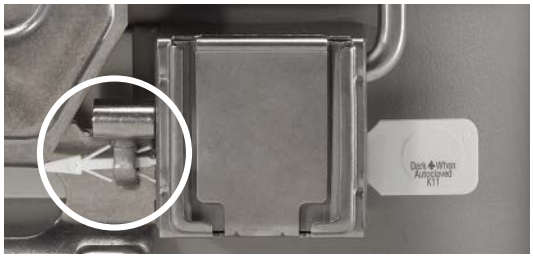
6.

Repeat steps 3 through 5 for the other end of the container.

When completed, the container should have two fully inserted and secured tamper-evident arrows in place.



Not Fully Inserted



Fully Inserted

CONTAINER CLEANING

After each use, the containers and the lifting platforms should be washed with a properly diluted, enzymatic / neutral pH detergent solution recommended for use on anodized aluminum. A neutral pH is defined as 7. The post-dilution pH level should not be below 7 or exceed 9.

Caution: A detergent with a highly acidic or highly alkaline pH could permanently damage the anodized finish of the container. Alcohol is not recommended for manual cleaning or wiping down. All cleaning agents should be thoroughly rinsed off prior to any sterilization process to remove all residual chemicals which could damage the protective anodized finish. Do not use abrasive cleaners, abrasive cleaning pads, or metal brushes on container surfaces. Use of these abrasive materials could potentially damage the protective anodized finish of the container.

DePuy Synthes Instruments and Implants should be reprocessed according to the instructions provided in the *Processing Synthes Reusable Medical Device – Instruments, Instrument Trays, and Graphic Cases (DJ1305) and the Processing Non-sterile Synthes Implants (DJ1304)* documents prior to being placed in a DePuy Synthes Container.

The container components may be processed in a mechanical washer or processed by hand. Do not clean the anodized container or container components (bottom, lid, retention plate, or optional protective plate) in an ultrasonic washer. Use of ultrasonic washer could potentially damage the protective anodized finish of the container.

PRE-CLEANING INSTRUCTIONS

It is recommended that containers be reprocessed as soon as is reasonably practical following use. Containers should be transported via the institution's established transport procedure.

Initiate cleaning of device within 2 hours of use.

Excess gross soil should be removed as soon as possible after use by rinsing or wiping the device.

All containers must be processed in the completely open and disassembled (i.e., taken-apart) configuration. Disassembly should not require any mechanical tooling (i.e., screwdriver, pliers, etc.) unless otherwise indicated.

CLEANING – MANUAL METHOD

1. Disassemble device, if device is able to be disassembled prior to cleaning.
2. Rinse soiled device under running cold tap water for a minimum of two minutes. Use a soft-bristled brush to assist in the removal of gross soil and debris.
3. Soak device in neutral pH enzymatic cleaner or detergent solution for a minimum of ten minutes. Follow the enzymatic cleaner or detergent manufacturer's instructions for use for correct exposure time, temperature, water quality and concentration.
4. Rinse device with cold water for a minimum of two minutes. Use a syringe, pipette, or water jets to flush lumens, channels and other hard to reach areas. Actuate joints, handles and other moveable device features, if applicable, in order to rinse thoroughly under running water.
5. Manually clean device for a minimum of five minutes in a freshly prepared neutral pH enzymatic cleaner or detergent solution. Use a soft-bristled brush to remove soil and debris. Actuate joints, handles and other movable device features to expose all areas to the detergent solution, if applicable. Clean device under water to prevent aerosolization of contaminates.

   Note: **Fresh solution is a newly-made, clean solution.**

6. Rinse device thoroughly with deionized (DI) or purified (PURW) water for a minimum of two minutes. Use a syringe, pipette or water jet to flush lumens and channels. Actuate joints, handles and other moveable device features in order to rinse thoroughly under running water, if applicable.
7. Visually inspect device. Repeat the manual cleaning procedure (steps 2-6) until no visible soil remains on device.
8. Perform a final rinse on device using DI or PURW water.
9. Dry device using a clean, soft, lint-free cloth or clean compressed air.

CLEANING – MECHANICAL METHOD: MECHANICAL WASHER

1. Disassemble device, if device is able to be disassembled, prior to cleaning.
2. Rinse soiled device under running cold tap water for a minimum of one minute. Remove gross soil using a bristled brush or soft lint-free cloth.
3. Manually clean device for a minimum of two minutes in a freshly prepared neutral pH enzymatic or detergent solution. Follow the enzymatic cleaner or detergent manufacturer's instructions for use for correct dilution, temperature, water quality and exposure time. Use a soft-bristled brush to remove soil and debris. Actuate joints, handles and other moveable device features to expose all areas to detergent solution. Clean device under water to prevent aerosolization of contaminants.

Note: **Fresh solution is a newly-made, clean solution.**

4. Rinse device using cold to lukewarm running tap water for a minimum of one minute. Use a syringe, pipette or water jet to flush lumens and channels. Actuate joints, handles and other moveable device features in order to rinse thoroughly under running water.
5. Visually inspect device.
6. Mechanical Washer process (Pre-cleaning steps 2-5 should occur prior to this step.):

Cycle	Minimum Time (minutes)	Minimum Temperature/Water	Type Detergent
Pre-Wash	2	Cold tap water	N/A
Wash I	2	Cold to Warm tap water	Neutral enzymatic pH between 7 and 9
Wash II	5	Warm tap water (>40°C)	Detergent with pH between 7 and 9
Rinse	2	Warm DI or PURW (>40°C)	N/A
Dry	40	90°C	N/A

7. Visually inspect device. Repeat steps 2 - 6 until no visible soil remains on device.

CONTAINER STERILIZATION

RECOMMENDED STERILIZATION CYCLE PARAMETERS

The following recommendations may include sterilization temperature/exposure parameters and maximum loads different than those which your institution commonly uses. Since individual sterilizers may perform differently, it is important to conduct individual sterilizer testing of containerized instrument sets using biological and chemical indicators to verify exposure times and to determine adequate sterilizing parameters in your particular facility.

These recommendations represent specific validated settings, but are not inclusive of all possible combinations of settings and variables which could produce acceptable results. The recommendations below were generated to cover a worst case DePuy Synthes Sterilization Container with typical load contents. The end user is ultimately responsible for establishing and following protocols to ensure properly sterilized and dried sets.

Sterilizers vary in design and performance characteristics. It is strongly recommended that the user verify the cycle parameters for the specific sterilizer prior to use. It is important to verify the parameters in conjunction with the sterilizer, load contents and any other processing accessories that may be used. Adjusted cycle times or dry times may be required to properly sterilize and dry desired loads.

SPECIFIC RECOMMENDATIONS FOR ACCESSORIES AND CONTAINERS

Pre-vacuum Steam Sterilization Cycle for all Perforated and Solid Bottom Containers

- Exposure Temperature 270°F (132°C)
- Preconditioning Pulses 3
- Exposure Time 4 minutes
- Minimum Dry Time Cycle with total weight of 25 lbs. (11.36 kg) 30 minutes*

*When applying dry times to DePuy Synthes instrument & implant sets and their accessories, dry times outside the standard healthcare pre-vacuum parameters may be required. The current recommended dry times for DePuy Synthes sets can range from a standard 20 minutes to an extended time of 60 minutes. The dry time is frequently influenced by the presence of polymer based (plastic) materials; therefore, changes such as reduced weight, and/or elimination of silicone mats can reduce necessary dry time. Dry times may be highly variable due to differences in environmental conditions, steam quality, device materials, total mass, sterilizer performance and varying cool down time. The user should employ verifiable methods (e.g. visual inspections) to confirm adequate drying.

PRECAUTIONS

- Do not obstruct the sterilant access holes. These holes allow the exchange of air and penetration of sterilant into and out of the container. When these access holes are blocked it can impede this exchange process. Under pre-vacuum steam, this blockage can cause the container to collapse.
- Stacking the containers during sterile processing is not permitted.
- No more than one (1) fully loaded graphic case can be placed directly into a DePuy Synthes Sterilization Container.
- Stand-alone modules/racks or single devices must be placed, without stacking, on a lifting platform to ensure optimal ventilation.
- Do not use adhesive tape on the container. Removal of adhesive residue may result in cosmetic damage to the container.
- The use of basket liners may cause condensate to pool.
- Sterilize container and contents using hospital protocol. Since sterilizers vary in design and performance characteristics, it is strongly recommended that the user verify the cycle parameters for the specific sterilizer and types of instruments being sterilized prior to use.
- DePuy Synthes Sterilization Containers are only approved for pre-vacuum steam sterilization. This information is located in the Sterility Assurance Instructions for Use (SA IFUs) which can be accessed through the DePuy Synthes Companies internet site, at the following address: http://www.synthes.com/cleaning-sterilization
- Only the recommended filters, tamper-evident arrows, data cards, lifting platforms and repair parts are validated for use with the DePuy Synthes Reusable Sterilization Container System. Do not use unauthorized single use accessories or container components.

WARNINGS

Do not use filter materials in the presence of flammable anesthesia. A safety hazard may occur.

LOADING AND COOLING

When fully assembled, the container is ready for sterile processing. DePuy Synthes Container is only indicated for pre-vacuum steam sterilization.

- The containers should be positioned flat on the cart and not placed on their sides or upside down.
- Do not place containers above wrapped items.

CAUTIONS

- Do not remove containers from the carrier until cool to touch or place warm containers on cold tabletops. Proper cool down is necessary to prevent wet sets or re-condensation from forming.
- Eliminate drastic temperature differences by keeping the containers away from cool ventilation ducts or cool drafts. Rapid cooling can cause condensation to form resulting in wet sets.
- Do not place processed containers into the sterile storage area until they reach room temperature.
- Make sure sterilant access holes (perforations) on the containers are not obstructed.
- Always practice safe lifting and handling of heavy objects.
- Minimum cool time: 60 minutes (may vary according to load contents).

CART LOADING GUIDELINES

Always place containers flat on shelves.

180-DAY EVENT-RELATED SHELF-LIFE STUDY

DePuy Synthes test containers were sterilized using pre-vacuum steam sterilization. The fully loaded containers were transferred to wire storage shelves and held for 180 days. The containers were periodically rotated to simulate normal handling and to provide an equal challenge to all units. After 180 days, the units were assessed for sterility. The contents of all containers were sterile, indicating that sterility was maintained for the indicated event-related shelf life duration.

Note: **Do not stack more than four (4) containers high during storage.**

CONTAINER ASEPTIC PRESENTATION

The DePuy Synthes Reusable Sterilization Container System provides the operating room personnel with an exterior tamper-evident arrow to help visually communicate that the container has been subjected to a sterilization process and has not been tampered with (opened) prior to its intentional opening at the point of use.

Chemical and/or biological indicators may be incorporated into the assembly process and provide critical information to the end user to establish whether the internal contents are safe to use. The indicator to be used is the decision of the hospital based on individual hospital protocol and current guidelines.

Inspection should also be conducted at the point of use to ensure that the filter has been inserted properly, that the retention plate is secure and there is no visible damage to the gasket found in the lid and that contents are dry. If the filter is missing, the retention plate is not secure, the gasket is visibly damaged, the arrow is missing or broken, or the dot has not changed color the container should be considered contaminated and not used.

Inspecting these external and internal devices is important prior to placing any contents into the sterile field. The container itself is not to be placed into a sterile field because the container exterior is not sterile.

In general, the contents are removed by carefully lifting them up and away from the container bottom edge (lip) and placed into the sterile field.

STERILITY MAINTENANCE GUIDELINES

The contents of a container should not be considered sterile if any of the following conditions are present:

- A filter is missing from any of the perforated areas.
- A retention plate is dislodged or not fully engaged.
- A filter does not cover the raised edges (filter ridge) surrounding the perforated areas on the lid or bottom.
- A filter is wet.
- A filter is damaged, torn, ripped, punctured, or creased (folded over onto itself).
- More than one filter per filter retention area is used for processing or the filter material has been folded forming more than one layer over the perforations.
- A filter has been reused.
- A tamper-evident arrow is missing or broken in either of the two data blocks.
- The indicator dot is missing from the tamper-evident arrow at the time of opening.
- The indicator dot does not indicate a noticeable color change.
- There is no internal chemical indicator found in the basket when opened (if hospital protocol dictates that one should be present).
- The internal chemical indicator (if present, per hospital protocol) does not indicate the item has been processed when used according to the manufacturer's recommendations for use.
- The gasket is either damaged or separated from its retaining groove.
- The bottom lip is damaged or dented causing a gap or break in the compression indentation in the gasket.
- There is residual water or condensation within the container at the point of use.

PREPARING FOR OPENING

Place the container on a level surface that facilitates aseptic opening.

EXTERNAL INSPECTION

1. Inspect the container per the Sterility Maintenance Guidelines before opening.
2. Check for the appropriate color change of the chemical indicator located on the tamper-evident arrow:

The indicator on the white arrow changes color in the half circle to a dark gray or black. (As long as there is a noticeable color change from white to dark, the steam indicator has reacted sufficiently to indicate the container was processed.)

Not Processed

Processed

Note: **A chemical indicator that has changed color differentiates a processed container from an unprocessed one. Chemical indicators are not an indication of sterility.**

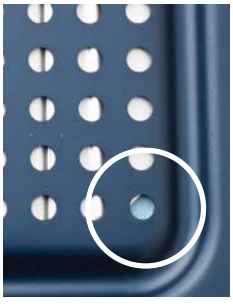
3. Check for the physical integrity of both tamper-evident arrows.
4. Grasp the arrow on the chemical indicator dot end and gently pull. If the arrow slips out of the channel, consider the contents of the container not sterile.

INSPECT FILTER PLACEMENT AND INTEGRITY

Inspect to ensure filters are in place.

- The filter color will show through the sterilant access holes (perforations) on the lid of the container and container bottom (if a perforated container bottom is used).
- If the optional protective plate was used in assembly of the lid, the filter color will show through a single corner of the sterilant access area.

Filter color shown through the sterilant access holes when the optional protective plate is not used.



Filter color shown through a single corner of sterilant access area when the optional protective plate is used.

INSPECT THE DATA CARD

Check for expiration date. Do not use if beyond expiration date.

OPENING THE CONTAINER (Non-scrubbed personnel)

1. Supporting the upper latch with thumb.
2. Place fingers under bottom latch on both ends of the container.
3. Gently pull upward and outward on bottom latch.

Simultaneously open both latches or open one side at a time. This disengages the lid from the bottom and breaks the tamper-evident arrow to enable opening of the container.

The lid handles will move to the full upright position.

REMOVING THE LID (Non-scrubbed personnel)

1. Place fingers into the opening on each of the lid handles. Lift lid vertically up and off the container bottom. After removing, inspect the container lid.
2. Inspect gasket to ensure there is no damage or separation from the retaining groove.
3. Inspect gasket to make sure the compression indentation is uniform around the gasket perimeter.
4. Inspect the filter(s) and retention plate(s) in the lid for correct placement.
5. Inspect the filter for any visible tears or punctures.

REMOVING THE CONTENTS (Scrubbed Personnel)

1. Check the internal chemical indicator (CI) for acceptable results (if present, per hospital protocol).
2. Remove the contents from the container.
3. Securely grasp the handles, making sure the sterile gown and gloves do not touch the outside of the container, the container edge (lip) or table.
4. Lift the contents in a straight upward direction.

   NOTE: If the lifting platform is used, ensure the lifting platform handles are angled toward the center during removal to prevent binding of lifting platform handles with container.

5. Discard filters and tamper-evident arrows.

ADDITIONAL INFORMATION

GENERAL PRECAUTIONS

Inspect, thoroughly clean, and rinse all reusable components (container, lifting platforms) before placing into service. Improperly preparing the DePuy Synthes Sterilization Containers may adversely affect the protective anodized finish.

The sterilization container should be routinely inspected for damage which could result in the product not functioning as intended, such as not closing properly or failing to maintain closure. Routine inspection of the gasket and lid will alert you to potential repair or replacement needs. Whenever you have questions about the proper functionality of the DePuy Synthes Sterilization Container System you should contact your local sales representative.

The disposable filters, tamper-evident arrows with process indicator and data cards are for **single use only. DO NOT REUSE.**

FILTER

Use only the filters available from the DePuy Synthes Companies that are designed for use with the DePuy Synthes Sterilization Container System. The use of other filters may compromise the sterilization process.

The 62.010.002 filter is required for use with the DePuy Synthes sterilization containers. One filter sheet, or thickness, should be used underneath each retention plate per process. Using more than one thickness or reusing the filter has not been validated for efficacy.

DATA CARD

The purpose of the data card is to record processing information such as load, date processed and expiry date, according to your facility's protocols. The data cards are inserted from the top into the data blocks located on the left side of each bottom container latch for easy visual access during storage and transport.

Note: Insert data card prior to attaching the lid to allow proper content identification. Always use a data card to record processing information. Do not reuse data cards.

LINERS

The use of absorbent or non-absorbent liners has not been validated in DePuy Synthes reusable rigid sterilization containers. DePuy Synthes Reusable Sterilization Containers have been validated for efficacy and dryness without the use of any liners, indicating that the use of liners is not necessary to achieve a dry set when processing according to our sterilization parameter recommendations.

LIFTING PLATFORMS

Select the appropriate lifting platform based on the size of the container. The extended lifting platform is for use with the extended containers. The full size lifting platform is for use with the full size containers.

Caution: **Use of a lifting platform is required when using a perforated bottom container, stand-alone module/racks, or single devices.**

WEIGHT

A validated total weight of 25 lbs. (11.36 kg) has been demonstrated for pre-vacuum steam using the most challenging DePuy Synthes Container from a sterilant penetration perspective.

Whenever possible, break up the overall density of the contents to achieve better drying results.

It may be necessary to adjust your set assembly practices to comply with current weight recommendations and guidelines. This adjustment may require you to break up overweight sets and reconfigure them into multiple container sets.

Consult with the device manufacturer to ensure the devices you are processing are compatible with the chosen sterilization process.

LIMITS OF REUSE

The sterilization container should be evaluated prior to each use to determine if there are any defects which could compromise performance. The parameters for evaluating the device components are presented below. If defects are observed, the use of the container should be discontinued.

ROUTINE INSPECTION

- **Inspect the container parts during cleaning and assembly. Do not use damaged or defective parts; replace damaged parts or send them for repair.**
- The container lid should demonstrate a noticeable bounce upon opening due to the downward compression created by the interlocking handles when closing. An absence of a noticeable bounce may indicate the need for gasket replacement or additional latch inspection.
- Inspect the edges of the container lid and bottom to ensure there are no sharp burrs or dents that may affect the gasket seal or proper lid closure.
- Inspect the gasket to ensure that it is free of cracks and tears, and that it is properly seated in its retaining groove.
- Inspect gasket for visible compression indentation formed by the upper lip of the container bottom. The compression indentation should be uniform and continuous around the entire gasket length.
- Routinely inspect retention plates to ensure proper locking mechanism function.

ADDITIONAL INFORMATION

Preventative Maintenance Checklist

The following should be routinely checked for proper container performance. A DePuy Synthes Container is not in good working order and should not be used if the following is observed in any of the areas indicated:

Lid

- Latch is bent.
- Latch cannot swing up and down freely.
- Latch spring is bent or protruding.
- Latch bracket is separated from lid.
- Gasket contains cuts or holes or is shredding.
- The seams of the gasket are separating.
- Gasket is not properly seated in retaining groove.
- Gasket exhibits visible degradation or color change.
- Dents, which could affect the gasket's sealing capabilities.

Bottom

- Latch is loose or separating from container.
- Handle sleeve is cracked or torn.
- Handle cannot swing up and down freely.
- Dents on upper lip of container, which comes in contact with the gasket.

Retention Plates

- Distorted shape.
- Bent lever.
- Lever does not secure plate properly under indent.
- Inadequate spring or compression.

Warranty

We guarantee every surgical device bearing the DePuy Synthes Companies brand name to be free of functional defects in workmanship and materials when used normally for its intended purpose. Any DePuy Synthes Companies device proving to be defective will be replaced or repaired at no charge.

Gaskets are warranted by the DePuy Synthes Companies for three (3) years from date of sale to be free of functional defects in both materials and workmanship.

Repairs or modifications performed by unauthorized personnel may void all product warranties and could affect performance and efficacy of device.

Return / Repair Policy

Contact your local sales representative or call DePuy Synthes Companies customer service at 800-523-0322.

Prior to returning any items for repair, authorization by the DePuy Synthes Companies is required. Pack containers securely to avoid damage during shipment. When shipping multiple containers in one carton, avoid metal-to-metal contact. Determination of credit amount or warranty repair/replacement will be made at the DePuy Synthes Companies facility.

IMPORTANT: All devices being returned for maintenance, repair, etc. must be cleaned and sterilized per instructions in this user's manual prior to shipment.

Product Return for Repair Information

- Parts that are faulty due to defects in material or workmanship will be repaired or replaced at no charge.
- Parts that have been misused or mishandled are not covered under warranty.
- Authorization is required before returning any item for repair or warranty replacement. Please contact your local sales representative or call DePuy Synthes Companies customer service at 800-523-0322 for a Return Goods Authorization number.
- Used or processed items may not be returned for credit.
- Clean and sterilize used components per instructions in this user's manual before returning for repair or replacement. Questionable items will be returned to sender.
- Wrap lifting platforms in protective foam before placing in the container to avoid internal shipping damage. Avoid metal-to-metal contact by securing retention plates and separating containers with cardboard dividers or similar protection.
- Lock the lid to the container bottom for shipment.
- Place container in plastic bag. Use protective packaging such as packing paper or foam to cushion the bottom of the box. Gaps around containers should be protected with packing to avoid internal movement.
- Do not use foam peanuts, newspaper or inflatable air packs.

If you are in need of proper shipping material, contact your local sales representative or call DePuy Synthes Companies customer service at 800-523-0322.

INDICATIONS

The DePuy Synthes Reusable Sterilization Container System is a device intended to be used to enclose other medical devices to be sterilized by a healthcare provider. It allows sterilization of the enclosed medical devices and maintains sterility of the devices until used for a maximum of 180 days.

DePuy Synthes Containers are suitable for dynamic air removal (pre-vacuum) steam sterilization when used according to the instructions for use.

Reusable lifting platforms are intended to hold enclosed medical devices above the filter areas of a perforated bottom container during sterilization and storage of the container.

Data cards are used to record information regarding a specific sterilization process load. Filter media allows ingress and egress of sterilant while providing a microbial barrier. Tamper-evident arrows provide a visual indication that the container system has not been inadvertently opened prior to use. Each arrow contains a modality-specific (pre-vacuum steam) external process indicator that serves as a visual indication that the system has been exposed to a specific sterilization cycle parameter. Data cards, filters, and tamper-evident arrows are single use only.

Sterilization Parameters and Devices Recommended for Use with System

Sterilization Parameters for the DePuy Synthes Reusable Sterilization Container

Applicable to both solid bottom and perforated bottom containers with lifting platforms

Sterilization Method	Cycle Parameters	Total System Weight	Types of Medical Devices and Materials Validated for Use with DePuy Synthes Container
Dynamic Air Removal (Pre-Vacuum) Steam	Exposure Temperature: 270°F (132°C) Pre-Conditioning Pulses: 3 Exposure Time: 4 Minutes Dry Time Cycle: 30 Minutes Minimum Cool Time: 60 minutes (may vary according to load contents) Stacking Not Permitted	25 lbs. (Container plus contents)	Orthopaedic Medical Devices including Lumen (Cannulated) Devices; Devices or Device Configurations with conjoined surfaces which meet, touch or unite; Mated Surfaces. Materials: Intrinsically stable metals. Composites, thermoplastics and thermosetting polymers with constant use temperatures above 135°C.

Examples of device types with conjoined or mated surfaces include forceps, clamps, bending pliers, and cable or plate cutters. Lumen devices include cannulated drill bits, guides, screwdrivers and cannulated screws; Dead end lumen (Ø2.1mm x 330mm); Open end lumens (Ø0.9mm x 278mm) (Ø1.1mm x 285mm), (Ø1.35mm x 278mm), (Ø3.65mm x 465mm), (Ø4.5mm x 438mm)

Examples of intrinsically stable metals include stainless steel, titanium (CP and alloys) and aluminum. Examples of thermoplastic polymers are PEEK, PEKK, PEI (Ultem™), Acetal (Delrin®), Radel® (PPSU), Nylon, PTFE, Polypropylene, ABS (Acrylonitrile Butadiene Styrene) and POM (Polyoxymethylene).

Examples of thermosetting polymers are Phenolic and Silicone.

Examples of composites include carbon fiber reinforced epoxy (CFRE).

DePuy Synthes Reusable Sterilization Container and Accessory Configurations Supported by Validation Data

MODALITY	DYNAMIC AIR REMOVAL (PRE-VACUUM) STEAM	
Type of Container	**Contents / Configuration**	**Validation Details**
Perforated Bottom Container and Solid Bottom Container	Lifting Platform	Yes
	Dead end lumen: Ø2.1mm x 330mm	Yes
	Open end lumens: Ø0.9mm x 278mm	Yes
	Open end lumens: Ø1.1mm x 285mm	Yes
	Open end lumens: Ø1.35mm x 278mm	Yes
	Open end lumens: Ø3.65mm x 465mm	Yes
	Open end lumens: Ø4.5mm x 438mm	Yes
	Mated Surfaces	Yes
	Materials: Intrinsically stable metals. Composites, thermoplastics and thermosetting polymers with constant use temperatures above 135°C.	Yes
	Filter	62.010.002
	Data Card	62.010.005
	Tamper-Evident Arrow	62.010.004
	Maximum Total Weight (Container plus Contents)	25 lbs.
	Stacking	Not permitted

DePuy Synthes Reusable Sterilization Container Compatibility, Contents, Accessories and Maximum Allowable Weight

Container	Lid	Compatible Graphic Case Footprint	Graphic Case Dimensions (L x W x H), in.	Contents	Required Accessories	Max. Weight (loaded)
Full-One Level, Perforated (62.006.001) or Solid Base (62.016.001)	Full Size	Half length, 1 high	10.5 x 9.8 x 2.0	Materials: Intrinsically stable metals. Composites, thermoplastics and thermosetting polymers with constant use temperatures above 135°C. Devices: Graphic Cases, Orthopedic Surgical Instruments, Implants Device Design Features: Mated Surfaces; Dead end lumen (Ø2.1mm x 330mm); Open end lumens (Ø0.9mm x 278mm) (Ø1.1mm x 285mm), (Ø1.35mm x 278mm), (Ø3.65mm x 465mm), (Ø4.5mm x 438mm)	2 Filters (Solid Base) 4 Filters (Perf. Base) Lifting Platform (Perf. Base) 2 Tamper-Evident Arrows	25 lb. (11.3 kg)
		2/3 length, 1 high	13.9 x 9.8 x 2.0			
		Full length, 1 high	20.7 x 9.8 x 2.0			
Full-Two Level, Perforated (62.006.002) or Solid Base (62.016.002)	Full Size	Half length, 2 high	10.5 x 9.8 x 3.4	Materials: Intrinsically stable metals. Composites, thermoplastics and thermosetting polymers with constant use temperatures above 135°C. Devices: Graphic Cases, Orthopedic Surgical Instruments, Implants Device Design Features: Mated Surfaces; Dead end lumen (Ø2.1mm x 330mm); Open end lumens (Ø0.9mm x 278mm) (Ø1.1mm x 285mm), (Ø1.35mm x 278mm), (Ø3.65mm x 465mm), (Ø4.5mm x 438mm)	2 Filters (Solid Base) 4 Filters (Perf. Base) Lifting Platform (Perf. Base) 2 Tamper-Evident Arrows	25 lb. (11.3 kg)
		2/3 length, 2 high	13.9 x 9.8 x 3.4			
		Full length, 2 high	20.7 x 9.8 x 3.4			
Full-Three Level, Perforated (62.006.003) Or Solid Base (62.016.003)	Full Size	Half length, 3 high	10.5 x 9.8 x 4.9	Materials: Intrinsically stable metals. Composites, thermoplastics and thermosetting polymers with constant use temperatures above 135°C. Devices: Graphic Cases, Orthopedic Surgical Instruments, Implants Device Design Features: Mated Surfaces; Dead end lumen (Ø2.1mm x 330mm); Open end lumens (Ø0.9mm x 278mm) (Ø1.1mm x 285mm), (Ø1.35mm x 278mm), (Ø3.65mm x 465mm), (Ø4.5mm x 438mm)	2 Filters (Solid Base) 4 Filters (Perf. Base) Lifting Platform (Perf. Base) 2 Tamper-Evident Arrows	25 lb. (11.3 kg)
		2/3 length, 3 high	13.9 x 9.8 x 4.9			
		Full length, 3 high	20.7 x 9.8 x 4.9			
Extended-Four Level, Perforated (62.009.004) Or Solid Base (62.019.004)	Extended	Half length, 4 high	10.5 x 9.8 x 6.3	Materials: Intrinsically stable metals. Composites, thermoplastics and thermosetting polymers with constant use temperatures above 135°C. Devices: Graphic Cases, Orthopedic Surgical Instruments, Implants Device Design Features: Mated Surfaces; Dead end lumen (Ø2.1mm x 330mm); Open end lumens (Ø0.9mm x 278mm) (Ø1.1mm x 285mm), (Ø1.35mm x 278mm), (Ø3.65mm x 465mm), (Ø4.5mm x 438mm)	2 Filters (Solid Base) 4 Filters (Perf. Base) Lifting Platform (Perf. Base) 2 Tamper-Evident Arrows	25 lb. (11.3 kg)
		2/3 length, 4 high	13.9 x 9.8 x 6.3			
		Full length, 4 high	20.7 x 9.8 x 6.3			
Extended-Five Level, Perforated (62.009.005) Or Solid Base (62.019.005)	Extended	Half length, 5 high	10.5 x 9.8 x 7.8	Materials: Intrinsically stable metals. Composites, thermoplastics and thermosetting polymers with constant use temperatures above135°C. Devices: Graphic Cases, Orthopedic Surgical Instruments, ImplantsDevice Design Features: Mated Surfaces; Dead end lumen (Ø2.1mm x 330mm); Open end lumens (Ø0.9mm x 278mm) (Ø1.1mm x 285mm), (Ø1.35mm x 278mm), (Ø3.65mm x 465mm), (Ø4.5mm x 438mm)	2 Filters (Solid Base) 4 Filters (Perf. Base) Lifting Platform (Perf. Base) 2 Tamper-Evident Arrows	25 lb. (11.3 kg)
		2/3 length, 5 high	13 .9 x 9.8 x 7.8			
		Full length, 5 high	20.7 x 9.8 x 7.8			

PRODUCT PART NUMBERS

DePuy Synthes Reusable Sterilization Container Descriptions and Dimensions

Part Number	Part Description	Volume to Vent Ratio (in3/in2)	Weight (lbs.)	Outer Dimensions (L x W x H), in.	Inner Dimensions (L x W x H), in.
Perforated Bottom Containers					
62.006.001	Full-One Level, Perforated Base	26	8.5	23.1 x 12.4 x 4.5	21.0 x 11.4 x 4.2
62.006.002	Full-Two Level, Perforated Base	31	8.8	23.1 x 12.4 x 5.3	21.0 x 11.4 x 5.1
62.006.003	Full-Three Level, Perforated Base	42	9.4	23.1 x 12.4 x 7.0	21.0 x 11.4 x 6.8
62.009.004	Extended-Four Level, Perforated Base	56	9.7	25.2 x 12.4 x 8.5	23.0 x 11.4 x 8.4
62.009.005	Extended-Five Level, Perforated Base	63	10.3	25.2 x 12.4 x 9.5	23.0 x 11.4 x 9.4
Solid Bottom Containers					
62.016.001	Full-One Level, Solid Base	52	7.8	23.1 x 12.4 x 4.5	21.0 x 11.4 x 4.2
62.016.002	Full-Two Level, Solid Base	62	7.9	23.1 x 12.4 x 5.3	21.0 x 11.4 x 5.1
62.016.003	Full-Three Level, Solid Base	83	8.5	23.1 x 12.4 x 7.0	21.0 x 11.4 x 6.8
62.019.004	Extended-Four Level, Solid Base	112	9.1	25.2 x 12.4 x 8.5	23.0 x 11.4 x 8.4
62.019.005	Extended-Five Level, Solid Base	126	10.0	25.2 x 12.4 x 9.5	23.0 x 11.4 x 9.4
Lifting Platforms					
62.006.010	Lifting Platform for Full Container	Not Applicable	2.6	20.5 x 10.6 x 1.3	Not Applicable
62.009.010	Lifting Platform for Extended Container	Not Applicable	2.9	22.5 x 10.6 x 1.3	Not Applicable

Additional Items in DePuy Synthes Reusable Sterilization Container System

Part Number	Part Description
Consumables	
62.010.002	Filters (1,000 pcs)
62.010.004	Tamper-Evident Arrows (1,000 pcs)
62.010.005	Data Cards (500 pcs)
Replacement Parts	
LIDS	
62.006.020	Lid for Full Sterilization Container
62.009.021	Lid for Extended Sterilization Container
BASES	
62.006.031	Perforated Base for Full-One Level Container
62.006.032	Perforated Base for Full-Two Level Container
62.006.033	Perforated Base for Full-Three Level Container
62.009.034	Perforated Base for Extended-Four Level Container
62.009.035	Perforated Base for Extended-Five Level Container
62.016.031	Solid Base for Full-One Level Container
62.016.032	Solid Base for Full-Two Level Container
62.016.033	Solid Base for Full-Three Level Container
62.019.034	Solid Base for Extended-Four Level Container
62.019.035	Solid Base for Extended-Five Level Container
FILTER RETENTION PLATES	
62.010.001	Optional Protective Plate
62.010.003	Filter Retention Plate, Top
62.010.006	Filter Retention Plate, Bottom

WARNING: In the USA, this product has labeling limitations. See package insert for complete information.

CAUTION: Some devices listed in this brochure may not have been licensed in accordance with Canadian law and may not be for sale in Canada. Please contact your sales consultant for items approved in Canada.

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